

REMARKS

The Office Action, including the Examiner's recommendation regarding indefiniteness, has been carefully considered. Claims 1 and 3-7 have been amended. New Claim 8 has been added.

Regarding the 35 U.S.C. § 112 rejection, the definition of "crystallinity" in the specification supporting the claims is obtained by measuring the water content of hydration in the aggregate using thermogravimetric analysis (see specification page 9 lines 26 to page 10 lines 16). In the claimed invention the crystallinity is the proportion of hydrate crystals to the aggregate, not based on the weight of the crude ergosterol in solution. With the definition of crystallinity incorporated in Claims 6 and 7, the indefiniteness rejection should be withdrawn.

Regarding the 35 U.S.C. § 102(b) rejections, the invention relates to a method of separating ergosterol from a solution containing ergosterol in a water-insoluble organic solvent, the method comprising supplying a very small amount of water such as a range wherein no phase separation to form two liquid phases occurs between the water-insoluble organic solvent and water in the solution, and precipitating ergosterol. Ergosterol precipitated and separated by the method of the present invention is a granular ergosterol aggregate with good solid-liquid separation character, and the aggregate comprises amorphous component and hydrate crystals.

In contrast to the Claim 1 invention, the Knol reference relates to a method of recovering and purifying ergosterol using zinc chloride. According to the Knol method, ergosterol is reacted with zinc chloride in iso-octane, obtained zinc chloride-ergosterol addition product is separated from reaction mixture and, then, ergosterol is recovered by decomposition of the addition product with water. Knol also discloses separation of ergosterol by solvent-solvent extraction using immiscible solvents such as iso-octane and water, but does not disclose controlling the amount of the water supplied within a range wherein no phase separation to form two liquid phases occurs between the water-insoluble organic solvent. It will thus be seen that the amended claims of the present invention are not anticipated by Knol.

Bills discloses removing ergosterol from a fungus fat saponification mixture containing acetone and an alkali metal hydroxide in alcohol by the addition of water, but does not disclose using water-insoluble organic solvent in this removing step. In Bills, it is explained that the crude ergosterol, which is prepared by the removing step, may then be purified by the method of a divisional application (Serial No. 355,440). The divisional Patent 1,755,548 (Serial No. 355,440) relates to the process of purifying ergosterol by cooling crystallization of ergosterol in an organic solvent such as alcohol, acetone, ether, benzene, etc using no water. The step of removing ergosterol in Bills and the step of purifying ergosterol in divisional Patent 1,755,548 are different steps. Neither Bills nor divisional Patent 1,755,548 even disclose adding water to water-insoluble organic solvent when ergosterol is removed or purified, much less controlling an amount of the water. Therefore, the amended claims are not anticipated by Bills.

Regarding the 35 U.S.C. § 103(a) rejections of Claims 1 and 3-8, in the method of Knol water is used for decomposition of the zinc chloride-ergosterol addition product or solvent-solvent extraction, as previously described. However, a skilled artisan would not have motivation, or any reasonable expectation of success, to control water in a very small amount because both decomposition and the extraction require a certain amount of water.

In the method of Bills, 500cc of acetone is added to fungus fat, the solution is mixed with alkali solution (25g alkali in 200cc of 95% ethanol) for the saponification of fats and, then, one liter of water is added to the saponification mixture to precipitate the ergosterol. Furthermore, Bills states that “If much less than one liter is employed ..., the ergosterol is incompletely precipitated ...”.

From the foregoing such descriptions, it is clear to the skilled artisan that Bills’ method needs a relatively large amount of water. Also, the skilled artisan would readily know that the mixture would be separated into two phases when the same amount of water as called for in the Bills’ method is added to the water-insoluble organic solvent described in Knol.

Furthermore, the ergosterol which is precipitated by the method of Bills is “an amorphous, light colored, flocculent mass (col. 2, lines 74-75)”, which has poor solid-liquid separation characteristics. On the other hand, ergosterol aggregates precipitated by the method of present invention have good solid-liquid separation characteristics. This

characteristic can be obtained by supplying water controlled within the range of amount wherein no phase separation occurs to form two liquid phases. It should thus be seen that the effect of the present invention is not disclosed or suggested by Knol and Bills. Accordingly, the present invention could not have been is obvious over Knol and Bills.

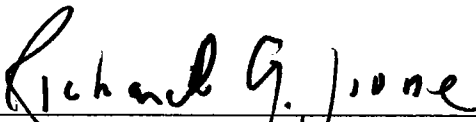
Regarding the 35 U.S.C. § 103(a) rejection based on Knol, Bills and Nimberger, Nimberger discloses a sampling pump which can be automatically discharge water from the regulator to a pressurized water container, but does not disclose or suggest that the sampling pump is suitable or is used for supplying water in precipitation process of an organic compound such as ergosterol. As such, Nimberger discloses nothing more than any instrument which may supply water. No motivation can be found to combine teachings of Nimberger to methods of Knol or Bills.

Regarding the 35 U.S.C. § 103(a) rejection of Claim 5 over Bills in view of Nimberger, primarily (as mentioned above) Bills does not disclose or suggest that the amount of water supplied is very small, such as a range wherein no phase separation can form two liquid phases. Furthermore, Bills does not disclose or suggest that water is supplied by moisturizing a gas phase portion in a system for precipitating ergosterol at all. Accordingly, the Claim 5 invention would not have been obvious to a skilled artisan, even if Knol and/or Bills references were combined.

Applicant respectfully submits that the invention now defined in amended Claims 1 and 3-8 have effectively been shown to be neither anticipated nor obvious in view of the prior art discussed. Accordingly, Claims 1 and 3-8 should be considered allowable.

Respectfully submitted,

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